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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,467	03/14/2001	Shyam Ramakrishnan	04974.00453	9773

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/805,467	RAMAKRISHNAN, SHYAM	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. Claims 1-7 and 11-62 have been cancelled as requested in the amendment filed on September 08, 2003. Claims 8-10 are pending in the instant application.

Claims 8-10 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on September 08, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

5. Claims 8-10 stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 2 of Paper No. 11. Specifically, the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

Applicant traverses the rejection on the premises that "[t[he specification discloses that human lipoxin A_4 receptor-like polypeptides "bind lipoxin A_4 or a lipoxin A_4 analog and...

mediate a biological effect, such as cyclic AMP formation, mobilization of intracellular calcium or phosphinositide metabolism" (page 3, last paragraph of the Response). Applicant further argues that because the activity of lipoxin A_4 receptor is known and disclosed, the activity of the protein that is similar in structure, lipoxin A_4 receptor-like protein of the instant invention precisely, is expected to be the same by virtue of structural similarity. These arguments were fully considered but are not deemed to be persuasive for the following reasons.

Contrary to Applicant's statement, the specific biological activity of the claimed lipoxin A_4 receptor-like polypeptides is never disclosed. Specifically, full text on page 9 quoted by Applicant, reads as follows:

"Preferably, a lipoxin A4 receptor-like polypeptide binds lipoxin A4 or a lipoxin A4 analog. Binding can be determined as described, for example, in the specific examples below.

Biologically Active Variants

Lipoxin A4 receptor-like polypeptide variants which are biologically active, *i.e.*, retain the ability to bind lipoxin A4 or a lipoxin A4 analog, and/or which mediate a biological effect, such as cyclic AMP formation, mobilization of intracellular calcium or phosphinositide metabolism, also are lipoxin A4 receptor-like polypeptides. Preferably, naturally or non-naturally occurring lipoxin A4 receptor-like polypeptide variants have amino acid sequences which are at least about 50, 55, 60, 65, 70, preferably about 75, 80, 85, 90, 95, 96, 97, 98, or 99% identical to the amino acid sequence shown in SEQ ID NO:2".

Furthermore, Example 3 on page 52 presents a protocol of how the activity of the instant claimed proteins can be assayed. "Receptor-mediated inhibition of CAMP formation can be assayed in LM(tk-)cells which express human lipoxin A4 receptor-like protein" (lines 11-12).

The instant specification, as originally filed, fails to present any evidentiary support that the instant lipoxin A_4 receptor-like polypeptides represent a functional novel receptor, as asserted by the specification. One skilled in the art readily understands that a polypeptide with structural similarity to the known functional receptor is capable of binding a ligand specific for that particular receptor. However, without full understanding of the following receptor mediated cascade and its significance to a particular specific physiological function which one would wish to manipulate for a desired effect, the precise biological function of the novel asserted receptor remains unknown.

Applicant submits that the present claimed polypeptides show structural similarity to "Gorilla low affinity N-formyl peptide receptor [...] with 27% identity and 47% homology", and, further, that "[l]ipoxin A_4 and N-formyl peptide receptors are known to be very slosely related [...] and N-formyl peptide receptors bind lipoxin" (page 5, first paragraph of the Response). However, based on the structural similarity between the instant polypeptide of SEQ ID NO: 2 and Gorilla low affinity N-formyl peptide receptor, one skilled in the art would only be able to conclude that these sequences could potentially be of the same evolutionary origin. There is no known knowledge in the art that would allow a conclusion that a protein that shows 27% structural identity to another protein, which in turn is closely related to a third protein, would possess the same biological function as the third protein, for which function is known and disclosed. If Applicant is aware of any art, which was available prior to the filing date of the instant application and supports such conclusion, then Applicant is strongly encouraged to make such art of record.

One would not have accepted the assertion that a protein of the instant invention is involved in signal transduction simply because there is experimental evidence of record, which supports such a conclusion. One would not have based that conclusion on the limited similarity between the amino acid sequence of SEQ ID NO: 2 and known GPCR receptors because it was known in the art prior to the time of the instant invention that sequence similarities of less than 40%between the amino acid sequences of two GPCRs were not predictive of a common class of ligand or a common physiological function. The Ross et al. publication (PNAS, 1990, 87:3052-56) described the isolation of a cDNA encoding a GPCR having 34% overall amino acid sequence identity to a putative angiotensin receptor; however, the protein encoded by that cDNA could not bind to angiotensins or transduce signal upon exposure to angiotensin. The Flumann et al. publication (BBRC, 1995, 206: 341-37) described the isolation of cDNA encoding a GPCR having 56% overall amino acid sequence identity to a calcitonin receptor; however, the protein encoded by that cDNA could not bind to calcitonin or transduce a signal upon exposure to calcitonin. The Eva et al. publication (FEBS Letts., 1990, 271(1, 2): 81-84) described the isolation of a cDNA encoding a GPCR having 33% amino acid sequence identity over the majority of its amino acid sequence to a neuromedin Y receptor; however, the protein encoded by that cDNA could ot bind to any of the known neuropeptides. The Gantz et al. publication (Genomics, 1997, 42 : 462-66) described the isolation of a cDNA encoding a GPCR having 34% overall amino acid sequence identity to a rat μ opioid receptor; however, the protein encoded by that cDNA could not bind to known opioid ligands. These references, taken in combination, show that an artisan of ordinary skill in the art of receptor molecular biology would not

reasonably conclude that a protein of the instant invention is a GPCR simply because it has 27% sequence identity to Gorilla low affinity N-formyl peptide receptor.

Thus, because at the time of invention a specific and "real world" utility for the instant lipoxin A_4 receptor-like polypeptides was not disclosed, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

6. Claims 8-10 stand rejected under 35 U.S.C. 112, first paragraph for reasons of record in section 3 of Paper No. 11. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

7. Claims 8 and 9 stand rejected under 35 U.S.C. 102(a) as being anticipated by Elshourbagy et al. (WO 00/26339, 05/2000) for reasons of record in section 4 of paper No. 11. Specifically, because the instant specification does not meet the requirements of 35 U.S.C. § 112, first paragraph, then the priority to the earlier provisional application is denied. Therefore, the effective filing date of the instant application is established as the filing date of the instant application, which is 03/14/2001, which constitutes Elshourbagy et al. as prior art under 35 U.S.C. 102(a).

Claim Rejections - 35 USC § 103

8. Claim 10 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Elshourbagy et al. as applied to claims 8 and 9 above and also in view of Hopp et al (US Patent No. 5,011,912, 1991) for reasons of record in section 5 of Paper No. 11.

Applicant traverses the rejection on premises that Elshourbagy et al. is not prior art for the instant claimed polypeptides (top at page 8 of the Response). This has not been found to be persuasive because, as fully explained earlier in this office action, Elshourbagy et al. is considered to be a valid prior art and, therefore, the instant rejection is maintained.

Conclusion

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. cc